UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

KEVIN CLARK and WILLIE MAE WILBURN, individually and on behalf of all others similarly situated, Plaintiffs, v. ACTAVIS GROUP et al., Defendants.	Case No. 2:08-cv-2293

AMICUS BRIEF OF THE UNITED STATES OF AMERICA

The United States of America, by and through its undersigned attorneys, respectfully requests that this Court consider the views expressed in this Amicus Brief regarding the pending motion that seeks to have Defendants in the above-captioned action be required to provide notice to unnamed class members. For the reasons discussed below, the United States Food and Drug Administration ("FDA") is concerned that the notice, as drafted by Plaintiffs, could confuse and potentially harm patients.

Factual History and FDA's Role

Plaintiffs in the above-captioned case have requested that the Court order Defendants to provide notice to potential class members and physicians regarding the drug product Digitek. Pls.' Order to Show Cause (June 3, 2008) (Dkt. #5). FDA is also aware that defendants, in their opposition brief, suggested that the Court request that FDA submit its views regarding Plaintiffs' motion. Defs.' Opp. to Pls.' Req. for Order to Show Cause (June 13, 2008) at 17 n.3 (Dkt. #14). Although FDA recognizes that Rule 23 provides authority for notice regarding certain matters, FDA is concerned that notices to potential plaintiffs that provide instructions or information

about actions with medical significance (such as discontinuation of use) that conflict with instruction already provided in the recall announcement have the potential to confuse patients. In this filing, FDA describes its role in the recall of products, as well as two specific examples of how the particular notice proposed in the present case creates the potential for patient confusion and harm.

Although FDA does not have direct statutory authority to require recalls of drug products, FDA has promulgated regulations setting forth recall procedures that include seeking the review and concurrence of FDA. See 21 C.F.R. §§ 7.40-7.59; see also Guidance for Industry: Product Recalls, Including Removals and Corrections (available at http://www.fda.gov/ora/ compliance_ref/recalls/ggp_recall.htm). As FDA explained in its preamble when it proposed these regulations, FDA views the removal from commerce of products that violate the Federal Food, Drug, and Cosmetic Act ("FDCA") as an essential part of its public health mission. See 41 Fed. Reg. 26924 (June 30, 1976).

Congress authorized FDA to remove violative drugs from the market by instituting seizure and injunction actions. See 21 U.S.C. §§ 332, 334. Because of the existence of these FDA-initiated enforcement tools and for other reasons (such as concerns for the public health and potential civil liability), regulated firms generally have cooperated with FDA in instituting recalls. See 41 Fed. Reg. 26924. From FDA's perspective, the advantage of a voluntary recall (as opposed to a civil seizure or injunction action) is that it removes violative products from commerce more expeditiously and effectively than those other measures. See id. at 26925-26; see also 21 C.F.R. § 7.40(c).

In the case of the recalled Digitek, FDA was consulted and concurred with the recall measures as appropriate for the situation. FDA continues its monitoring of this recall and other efforts to assure full regulatory compliance and resolution of all aspects of the violations

identified in this investigation. FDA does not have any information that would indicate that another notice at this time would add any benefit to the public health, and is concerned that it might confuse patients and potentially lead to adverse consequences.

The Proposed Notice and Public Safety

FDA believes that at least two features of the proposed notice may be contrary to the public health objectives of the recall procedures.

First, Plaintiffs request that patients be instructed to "retain and keep" Digitek and "not return" the product to the manufacturer. See Pls.' Order to Show Cause at ¶ 10. This direction differs from the instructions contained in recall notices already issued, and therefore may be confusing to the public.

Actavis Totowa initiated a Class I nationwide recall of all Digitek products on April 25, 2008. See Press Release (Apr. 25, 2008) (available at http://www.actavis.us/en/media+center/newsroom/articles/digitek+recall.htm). The press release advised retailers to return the product to the place of purchase and directed customers to contact Stericycle, the recall coordinator retained by Actavis, for more information. See id. Stericycle provides consumers instructions for returning unused product and obtaining a refund. See Affidavit of Michael M. Weinkowitz, Ex. 7 (June 3, 2008) (Dkt. #5). Plaintiffs' proposed new instruction to retain the product would switch course more than two months after the recall began.

More fundamentally, however, Plaintiffs' requested instruction that patients retain the defective drug product is contrary to the essential public health purpose of a recall – the removal of violative (and potentially harmful) drugs from commerce and from patients' medicine cabinets. Many of the patients who were prescribed Digitek are likely still in need of similar medication, and patients who retain super-potent Digitek may inadvertently ingest it. Although FDA recognizes the inherent authority of a court to order that parties to litigation preserve

evidence in their possession, custody or control, FDA believes that patients should not be directed to retain products that are subject to a recall.

Second, certain additional information in the proposed notice, as drafted, may confuse patients. For example, paragraph 1 of the proposed notice lists specific lot numbers for "affected Digetik," but the firm's recall covered *all* lots. Further, paragraphs 3 and 4 of the proposed notice seem to provide conflicting directions: Paragraph 3 directs patients to discontinue Digitek immediately, whereas paragraph 4 warns against the sudden discontinuation of Digitek. In FDA's view, and as reflected in the recall press release, the essential and primary message should be for patients to contact their physicians rather than make medical judgments on their own. However, the positioning of the information and use of enhanced type and font for certain statements in the proposed notice (e.g. **"YOU SHOULD NOT BE TAKING DIGITEK NOW"**) de-emphasizes and contradicts the message that patients should first contact their physician. Accordingly, the proposed notice could weaken that essential public health message.

In sum, the United States requests that the Court not order Defendants to provide a notice, such as that drafted by Plaintiffs' counsel, that confuses consumers regarding recall procedures or medical issues. FDA is concerned that providing such notice creates the potential for patient harm. Should the Court find that a notice is warranted for some other purpose, such as the preservation of evidence, that objective could be accomplished without risking unnecessary and potentially dangerous consumer confusion.

DATED this 14th day of July, 2008.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on July 14, 2008, a copy of the foregoing AMICUS BRIEF OF THE UNITED STATES OF AMERICA was filed electronically in accordance with the Court's Electronic Filing Guidelines. By operation of the Court's electronic filing system, notice of this filing will be sent to:

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